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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,311	10/23/2003	Raymond E. Counsell	66254-5003-US01	8570

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
05/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/692,311	Applicant(s) COUNSELL ET AL.	
	Examiner D. L. Jones	Art Unit 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *27 February 2008*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   HAS BEEN ENTERED

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *51-82 and 84-146*.
   Claim(s) withdrawn from consideration: *48,49 and 83*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

    _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s): _____
13. ☒ Other: see the attached response to the amendment filed 2/27/08.

4/14/08

/D. L. Jones/ 4/14/08
Primary Examiner
Art Unit: 1618

Continuation of 5. Applicant's reply has overcome the following rejection(s): the 112 first paragraph rejection are overcome because Applicant amended the claims to overcome the rejection.

Reponse to the amendment/arguments filed 2/27/08.

Claims 48, 49, and 51-146 are pending.

Claims 48, 49, and 83 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

Double Patenting Rejection: The rejection of claims 51-53, 55-68, 70-89, 91-104, and 106-123 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-6 of US Patent No. 6,645,463 is MAINTAINED for reasons of record in the office action mailed 8/27/08. It is duly noted that in Applicant's response filed 2/27/08, Applicant stated that a terminal disclaimer would be filed once the claims are indicated as allowable and only the double patenting rejection remains.

112 First Paragraph Rejection: The 112 first paragraph rejection is WITHDRAWN because Applicant amended the claim to overcome the rejection.

103 Rejection: The rejection of claims 51-82 and 84-146 under 35 USC 103(a) as being unpatentable over Modi (US Patent No. 6,214,375) in view of Wheeler et al (Journal of Pharmaceutical Sciences, 1994, Vol. 83, No. 11, pp. 1584-1564) is MAINTAINED for reasons of record in the office action mailed 8/27/08 and those set forth below.

In summary, Applicant asserts that while Wheeler et al discloses the use of [14C]triolein as a radioactive marker, there is no motivaiton for combining the references suggested by the Examiner. Applicant emphasizes that Modi teaches the use of liposomes as carriers for medicinally active agent. In addition, Applicant asserts that liposomes are distinct from oil-in-water emulsions, thus, the references should not be combined. Applicant also asserts that the liposomes of Modi were designed for a purpose different from that of Wheeler et al. Furthermore, Applicant asserts that in the psot-KSR landscape, it remains improper to combine references where the references teach away from their combination.

Applicant's arguments are non-persuasive for the following reasons. First, the basis of combining the references is that they disclose overlapping components.In the Wheeler document, triolein is labeled to allow one to conduct diagnostic/therapeutic testing on a subject. The form of Applicant's composition is not distinguished over the composition of the cited prior art because Modi discloses that their formation may be in various forms depending on the particular compositon of the formulation (column 4, lines 11-13). In addition, the skilled artisan would recognize that in order for a new physical form to be patentable, it must be more efficacious or possess new properties by a combination with other ingredients and not merely a change of form which has the advantages which one skilled in the art would expect from the change (Glue Co. v. Upton (USSC 1878) 97 US 3, 24 L Ed. 985). Furthermore, it should be noted that the prior art was combined to yield a predictable result because (1) the prior art included each element claimed although not necessarily in a single reference. (2) One of ordinary skill in the art could have combined the elements especially since the missing element of the primary reference is that the triolein is not labeled instead of a labeled triolein as set forth in Wheeler et al. The labeled triolein of Wheeler is used as a radiotracer. Thus, a skilled artisan would recognize that if the same substance is added (i.e., triolein), it would behave the same in both compositions, but the presence of the labeled triolein would enable one to follow the compositon of Modi throughout the body. Furthermore, if the compositions of the prior art are administered for medical puropses, then if the labeled triolein is administed, one of ordinary skill would recognize that tracking the biological path of the composition is possible. Hence, the 'improved' element (labeled triolein), although known in the art, would allow one to not only administer the composition of Modi, but to track its location in the subject. (3) Hence, a skilled artisan would recognize that the results from the combination (replacing the non-labeled triolein of Modi with [14C]triolein of Wheeler) would result in a predictable result. Thus, the rejection is deemed proper.

DAMERON L. JONES
PRIMARY EXAMINER